

### **REMARKS**

Claims 1-15 and 21-38 are currently pending in the present application. To the extent not superseded by Remarks made herein, Applicants incorporate by reference their Remarks made in the Amendment "A" and Response filed February 27, 2003, and Amendment "B" and Response filed October 6, 2003. Although Applicants believe the previously pending claims were patentable over the cited art of record for the reasons presented in the previously filed Amendment "A" and Response and Amendment "B" and Response, the following remarks are presented to further the prosecution of this case and obtain prompt allowance of the present claims. Accordingly, favorable reconsideration of the pending claims is respectfully requested.

#### ***Claims 1, 7-11, 21, 29 and 32***

Claims 1, 7-11, 21, 29 and 32 are rejected under 35 U.S.C. §§102(e) and 103(a) as being anticipated and/or rendered obvious, respectively, by United States Patent No. 6,069,172 issued to Bertini et al. ("Bertini"). The Office Action notes that "Bertini does not teach that the cellulose and the maltodextrin slow the disintegration of the orally administered specimen to provide a sustained release of the bioactive substance," but then asserts that a prima facie case of anticipation or obviousness has been established as "the claimed and prior art products are identical or substantially identical in composition..." See Office Action, p. 3 (citing In re Best, 562 F.2d 1252, 1255, 195 U.S.P.Q. 430, 433 (CCPA 1977)). Applicants respectfully disagree with the alleged finding of anticipation and obviousness as the claimed and prior art products are not identical or substantially identical in composition.

Bertini does not teach or disclose the claimed range of cellulose or the ratio of cellulose to maltodextrin. Further, Bertini does not teach or disclose the combination of cellulose and maltodextrin. Bertini merely includes a list of potential ingredients to be used as a supporting

mass for a slow-release active drug. See Bertini, col. 10, ll. 39-43. This list includes cellulose and maltodextrin, among many others, as potential excipients, but does not teach or suggest a formula, ratio or combination for producing a sustained release composition for use as an excipient, as claimed. In addition, Bertini requires the presence of a binding substance. See Bertini, col. 10, ll. 43-46. The stated test as to whether a reference declares an applicant's invention 'not novel' or 'anticipated' "is whether the reference contains an enabling disclosure" such that the "public was in possession of the claimed invention before the date of invention." M.P.E.P. § 2121.01 "Such possession is effected if one of ordinary skill in the art could have combined the publication's description with his [or her] own knowledge to make the claimed invention." M.P.E.P. § 2121.01 (citing In re Donohue, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985)). Bertini does not teach or disclose the combination of cellulose and maltodextrin, as recited in independent claims 1 and 21. Therefore, it would not have been obvious to one of ordinary skill in the art to take the grocery list of Bertini to make the recipe of the claimed excipient.

Accordingly, Applicants respectfully submit that independent claims 1 and 21, and any claims depending therefrom, are neither disclosed nor obvious variations of the product in Bertini.

***Claims 21-23 and 29-32***

Claims 21-23 and 29-32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bertini and United States Patent No. 5,128,143 issued to Baichwal et al. ("Baichwal"), for the reasons set forth on pages 4-5 of the Office Action. Applicants respectfully disagree as the proposed combination does not teach all of the recited limitations of independent claim 21, from which 22, 23 and 29-32 depend. As noted previously, Bertini

merely teaches a list of potential excipients for use as a supporting mass for an active drug and does not teach a sustained release time period (Office Action, p. 4). Baichwal cannot cure the deficiencies of Bertini, as Baichwal only teaches the use of a heteropolysaccharide (galactomannan) and optional inert filler (a monosaccharide such as dextrose). See Baichwal, col. 4, ll. 15-23 and 52-60.

More specifically, the cited references do not teach or suggest a sustained release orally administered composition comprising a excipient portion including a combination of a specific range of cellulose and a ratio of cellulose to maltodextrin, such that “the maltodextrin and the cellulose slowly disintegrate in an aqueous medium and thereby provide the sustained release of the bioactive substance over a time period ... wherein the cellulose and the maltodextrin are mixed with the bioactive substance throughout the orally administered specimen such that, upon ingestion, the orally administered specimen gels to prevent direct contact between a substantial amount of the bioactive substance and a stomach wall” as recited in claim 21. Accordingly, it is respectfully submitted that the rejection of claims 21-23 and 29-32 based upon 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn.

#### ***Claims 1 and 7-11***

Claims 1 and 7-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over United States Patent No. 5,470,581 issued to Grillo et al. (“Grillo”), for the reasons set forth on page 5 of the Office Action. Applicants respectfully disagree as Grillo does not teach or suggest all of the recited limitations of independent claim 1, from which 7-11 depend. Grillo is entirely focused on coatings and their respective properties, as previously noted in Amendment “B” and Response, filed on October 6, 2003. There is no suggestion or motivation anywhere in Grillo to move from making “coatings” and optimizing the properties of the “coating films” to

making a sustained release composition for use as an excipient of an orally administered specimen to be mixed with a bioactive substance, as recited in Claim 1. Further, Grillo in no way teaches or suggests the use of cellulose and maltodextrin to obtain sustained release features. It is respectfully submitted that the rejection of claims 1 and 7-11 based upon 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn.

***Claims 21-23 and 29-32***

Claims 21-23 and 29-32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Grillo and Baichwal, for the reasons set forth on pages 5-6 of the Office Action. Applicants respectfully disagree as the proposed combination does not teach or suggest all of the recited limitations of independent claim 21, from which 22, 23 and 29-32 depend. As previously noted, Grillo is entirely focused on “coatings” and does not teach the use of cellulose and maltodextrin to obtain sustained release or gelling features. Baichwal cannot cure the deficiencies of Grillo, as Baichwal only teaches the use of a heteropolysaccharide (galactomannan) and optional inert filler (a monosaccharide such as dextrose). See Baichwal, col. 4, ll. 15-23 and 52-60.

Neither Grillo nor Baichwal teach or suggest that the combination of cellulose and maltodextrin would function as a sustained release excipient. In addition, the combined cited references do not teach or suggest a sustained release orally administered composition comprising an excipient portion (cellulose and maltodextrin) and a bioactive substance “such that the maltodextrin and the cellulose provide in an aqueous medium the sustained release of the bioactive substance for a time period” and “wherein the cellulose and the maltodextrin are mixed with the bioactive substance throughout the orally administered specimen such that, upon ingestion, the orally administered specimen gels to prevent direct contact between a substantial

amount of the bioactive substance and a stomach wall,” as recited in claim 21. It is therefore respectfully submitted that the rejection of claims 21-23 and 29-32 based upon 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn.

***Claims 2-6, 33 and 35-38***

Claims 2-6, 33 and 35-38 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bertini and United States Patent No. 6,417,227 issued to Lord et al. (“Lord”), and/or Grillo and Lord, for the reasons set forth on pages 6-7 of the Office Action. Applicants respectfully disagree as neither of the proposed combinations teach all of the recited limitations of independent claims 1 and 33, from which 2-6 and 35-38 respectively depend.

As previously noted, Bertini does not teach or suggest the claimed range of cellulose or the ratio of cellulose to maltodextrin, or the combination of cellulose and maltodextrin, as recited in independent claims 1 and 33. Grillo is entirely focused on coatings, including tensile strength, modulus of elasticity and clarity. See Grillo, col. 5, ll. 15-28. To that end, Grillo requires the use of both a plasticizer (see col. 2, ll. 6-8) and water, components necessary to form a coating suspension but not required for use with sustained release tablets. Further, Grillo does not provide for sustained release, as recited in claims 1 and 33, and would not protect a stomach wall from direct contact with a medicine or a supplement, as recited in claim 33.

Lord cannot cure the deficiencies of Bertini or Grillo. Lord discloses a method of delivery of cetyl myristoleate. More specifically, Lord teaches an “oral medicament comprising cetyl myristoleate and an enteric coating. The enteric coating is resistant to dissolution in the stomach but predisposed to dissolution in the intestine so as to prevent release of the cetyl myristoleate until the medicament is in the intestine.” Lord, col. 2, ll. 44-48. Lord also identifies a number of materials that can be used to form the enteric coating, but states that “[t]he choice of

enteric-coating materials is not of significance as long as release is delayed until the formulation reaches the small intestine.” Lord, col. 8, ll. 8-19. Therefore, Lord does not teach or suggest a sustained release composition “wherein the cellulose and the maltodextrin are mixed with the glucosamine-based substance throughout the orally administered specimen” as recited in claim 33 or “wherein the cellulose and the maltodextrin are mixed with the bioactive substance throughout the orally administered specimen,” as recited in claim 1.

Accordingly, Applicants respectfully submit that independent claims 1 and 33, from which 2-6 and 35-38 respectively depend, are neither disclosed nor obvious variations of Bertini or Grillo and Lord alone or in combination. It is respectfully submitted that the rejection of claims 2-6, 33 and 35-38 based on 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn.

***Claims 12-15, 24-28 and 34***

Claims 14, 15 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Grillo and Lord in view of Grain Processing Corporation. The Office Action notes that Grillo and Lord are silent as to the teaching of the claimed maltodextrin, and then goes on to explain how Grain Processing Corporation overcomes this deficit. See Office Action, p. 7. Applicants respectfully disagree as the proposed combination does not teach all of the recited limitations of independent claims 1 and 33, from which 14 and 15 and 34 respectively depend.

Claims 24-28 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Grillo, Baichwal and Lord for the reasons set forth on page 8 of the Office Action. The Office Action notes that Grillo and Baichwal are silent as to the teaching of the claimed specific agent, and then goes on to explain how Lord overcomes this deficit. See Office Action, p. 8.

Claims 12 and 13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Grillo and Bertini for the reasons set forth on pages 8-9 of the Office Action. The Office Action notes that Grillo does not teach the claimed cellulose polymer, and then goes on to explain how Bertini overcomes this deficit. See Office Action, pp. 8-9. For the reasons presented hereinabove with respect to the independent claims 1, 21, and 33, none of Grillo, Lord, and Baichwal teach or suggest the foregoing discussed limitations of claims 1, 21, and 33. In addition, Grain Processing Corporation and Bertini cannot overcome these deficiencies. Grain Processing Corporation merely discloses the characteristics of various edible maltodextrin compositions and Bertini merely provides a list of possible excipients to be used as a supporting mass for an active drug.

Accordingly, Applicants respectfully submit that independent claims 1, 21, and 33, as presented herein, and any claims depending directly or indirectly therefrom, are neither disclosed nor obvious variations of the structure in Bertini, Grillo, Lord, Baichwal, and Grain Processing Corporation, alone or in combination.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 30<sup>th</sup> day of June, 2004.

Respectfully submitted,



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